K000256

FEB 11 2000

510(k) Summary of Safety and Effectiveness

Trade Name:	Cap PORPs and TORPs
Common Name:	Partial/Total Ossicular Replacement Prosthesis
Classification Name:	Partial Ossicular Replacement Prosthesis (§ 874.3450) Total Ossicular Replacement Prosthesis (§ 874.3495)
Official Contact:	Alicia E. Farage Senior Regulatory Affairs Specialist Smith & Nephew, Inc. ENT Division 2925 Appling Road Bartlett, TN 38133
Telephone:	(901) 373-0200
Telefax:	(901) 373-0242
Date Prepared:	January 27, 2000.

The Cap PORPs and TORPs are substantially equivalent to the Black Oval-Top PORPs and TORPs marketed by Smith & Nephew, Inc., ENT Division, and the Moretz Peg-Top® Partials and Totals implants marketed by Xomed. These devices have the same indications for use, total reconstruction of the ossicular chain that has lost its function due to disease, trauma, or congenital defect. The heads of the Cap PORPs and TORPs Prostheses are made from Hydroxylapatite, a widely accepted material for middle ear reconstruction, as are the heads of the Black Oval Top predicate devices. The Cap PORPs and TORPs Prostheses and the Moretz Peg-Tops predicate devices all have a pedestal on the head and trimmable shafts. The Cap PORPs and TORPs implant shafts are made from HAPEX and the Moretz Peg-Tops implants shafts are manufactured Polycel.

Differences between the Cap PORPs and TORPs and the predicate devices should not affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2000

Ms. Alicia E. Farange
Senior Regulatory Affairs Specialist
Smith & Nephew, Inc.
2925 Appling Road
Bartlett, TN 38133

Re: K000256
Trade Name: Cap PORP® and TORP®
Regulatory Class: II
CFR: 874.3540 and 874.3495
Product Code: 77ETB and 77ETA
Dated: January 27, 2000
Received: January 28, 2000

Dear Ms. Farage:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number:
Device Name: Cap PORP® and TORP®

Indications For Use:

- Otosclerosis
- Congenital fixation of the stapes
- When previous remedial surgery has been unsuccessful for the treatment of hearing loss due to otosclerosis, and a significant conductive loss remains with good cochlear reserve.
- Chronic middle ear disease
- Trauma

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K000256